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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,691

Applicant(s)

GULLANS ET AL.

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-151 is/are pending in the application.
- 4a) Of the above claim(s) 13-151 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-12 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' election without traverse of Group I (claims 1-12), drawn to a method of inhibiting death of a neuronal cell comprising administering a composition comprising a steroid composition in Paper No.8 is acknowledged. Accordingly, claims 13-151 have been withdrawn from consideration since they are non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Washburn et al. (U.S.Patent No. 5,719,137) of record.

Washburn et al. teach a method of using therapeutically effective amounts of a steroidal compound to prevent and treat neurodegeneration including Alzheimer's disease. (abstract, column 3, lines 21-65). The sufficient dosage set forth in claims 3 and 4 are encompassed by the "therapeutically" effective amounts administered by Washburn et al. in the treatment of neurodegeneration in Alzheimer's disease.

Claims 1-4, 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Bender et al. (U.S.Patent No. 5,998,638) of record.

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Bender et al. teach that progestinal agents (progestin) are useful in treating Alzheimer's disease and other central nervous system disorders. (abstract, column 2, lines 29-40). Bender et al. also teach the daily dosage requirements for the treatment of Alzheimer's disease and other central nervous system disorders. (column 3, lines 53-60).

Claims 1-3, 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Simpkins (U.S. Patent No. 5,843,934) of record.

Simpkins teaches a method of protecting a population of nerve cells from death by administering to a nerve cell population in a human subject an effective dosage of an estrogen compound (steroid) sufficient to protect a nerve cell death. (column 3, line 62- column 4, lines 63, column 5, lines 12-23). Simpkins teaches that estrogen compounds are useful for neurodegenerative diseases including Alzheimer's disease, Parkinson's disease, diabetic peripheral neuropathy, multiple sclerosis, amyotrophic lateral sclerosis, stroke and hypoxia. (column 5, lines 12-23, column 7, lines 23-48). The sufficient dosage set forth in claims 3 and 4 are encompassed by the effective amounts administered by Simpkins in the treatment of a population of nerve cells to protect a nerve cell death.

Claims 1-3, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Christensen et al. (WO 95/10527) of record.

Christensen et al. teach that steroids and their therapeutic uses in protecting against encephalitis and meningitis. (page 1, lines 10-11, page 4, lines 21-25). Christensen et al. also teach the amount of active agents that are effective and safe for use in human in treatment of above disorders. (page 6, lines 4-11). Applicant's mechanism of action of inhibiting oxidative

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stress-induced cell death and inhibiting apoptotic death of neuronal cell would be an inherent effect of the treatment of encephalitis and meningitis with effective dosage administered by Christensen et al.

Claims 1-3, 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Farb (WO 97/03677) of record.

Farb teaches that pregnenolone (progestin compound) can be use for the treatment of any neuropathic pain, neurodegenerative diseases such as Parkinson's disease, Alzheimer's disease, and amyotrophic lateral sclerosis, stroke, ischaemia, and brain cell death. (page 55, claim 22).

Claims 1-3, 6, 8, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Tuor et al. (1996) of record.

Tuor et al. teach the use of effective amounts of corticosterone or dexamethasone (anti-inflammatory steroid) for the treatment of cerebral hypoxia-ischemia. (abstract). Applicant's mechanism of action of inhibiting oxidative stress-induced cell death and inhibiting apoptotic death of neuronal cell would be an inherent effect of the treatment of cerebral hypoxia with effective dosage administered by Tuor et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokuda et al. (XP 2201620) in view of Sekut et al. (U.S. Patent No. 6054487).

Tokuda et al. teach that anti-inflammatory medications such as corticosteroid decrease the incidence of Alzheimer's disease.

Tokuda et al. do not teach flunisolide for the treatment of Alzheimer's disease.

Sekut et al. teach that flunisolide is one of the corticosteroid. (column 5, lines 4-7).

It would have been obvious to one of ordinary skill in the art to employ flunisolide for the treatment of Alzheimer's disease because Tokuda et al. teach that corticosteroid in general are useful for the treatment of Alzheimer's disease and because Sekut et al teach that flunisolide is

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one of the corticosteroid. One would have been motivated to employ any corticosteroid (e.g. flunisolide) for the treatment of Alzheimer's disease to achieve expected benefit for the treatment of Alzheimer's disease as taught by Tokuda et al. Absent any evidence to contrary, there would have been reasonable expectation of success in treating Alzheimer's patients of Tokuda et al. with a corticosteroid (e.g. flunisolide).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Allowable Subject Matter

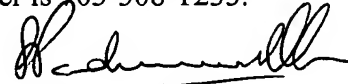
Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

9/8/03

Jmk
September 5, 2003